

REMARKS

Applicants submit this paper is submitted in response to the Office Action the Office mailed on June 23, 2005.

Support for the dosages recited at new claims 50, 63, 64 and 67 is at least at paragraphs 218, 317, 355, 599 and 623. Support for the numbers of days of dosing at new claims 64, 65, 67, 78 and 79 is at least at paragraphs 222, 223 and 592. Support for the clinical indications at new claims 51 and 68 is at least at paragraphs 223, 229, 354 and 549. Support for the R⁴ moieties recited in new claims 50 and 67 is at least at paragraph 149. Support for the chemical structures at new claims 50, 56, 59, 67, 71 and 74 is at least at paragraphs 149, 364, 432-433, 438 and 443. Support for increased numbers of neutrophils in circulation recited in new claims 50 and 67 is at least at paragraph 556. The amendments introduce no new matter.

Restriction requirement

In the action mailed on June 23, 2005, the Office imposed and made final a restriction that required the variable group R⁹ to be -CHR¹⁰-. Applicants have amended the claims to conform to this requirement.

Nonstatutory double patenting

The Office provisionally rejected claims 29-34, 36, 39 and 40 under judicially created obviousness-type double patenting over claims 1-4 and 9-11 of copending application No. 10/651,515. Applicants respectfully traverse the rejection and note that this rejection is not procedurally ripe for consideration.

Because of this, Applicants request the Office to hold this provisional rejection in abeyance until patentable subject matter is identified in either or both of these applications. The filing of a terminal disclaimer at this time is premature. Once patentable subject matter is identified, Applicant can properly address this issue, the terms of which will depend on the scope of allowable subject matter in these applications.

35 U.S.C. § 102(b)

The Office rejected claims 29-34, 36, 39 and 40 as allegedly anticipated by U.S. patent No. 5,461,042 (hereafter '042). Applicants respectfully traverse the rejection.

5 A prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently, to anticipate. *Telemac Cellular Corp. v. Topp Telecom, Inc.* 247 F.3d 1316, 247 F.3d 1316; 2001; 58 USPQ2D 1545-1558 U.S.P.Q.2D (Fed. Cir. 2001) citing *In re Schreiber*, 128 F.3d 1473, 1477, 44 U.S.P.Q.2D 1429, 1431 (Fed. Cir. 1997). Under the principles of inherency, if the
10 prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates. *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365, 52 U.S.P.Q.2D 1303, 1305 (Fed. Cir. 1999). Inherent anticipation thus requires that a missing characteristic is necessarily present, or inherent, in the single anticipating reference. *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d
15 1373, 1377 (Fed. Cir. 2003).

New claims 50-66 recite a specified dose range, which the '042 patent does not expressly or inherently disclose. The protocols in '042 at examples 1, 2, 5, 6, 7, 8 disclosed doses of compound per mouse, but the weight of the animals is not disclosed. Therefore, examples 1, 2, 5, 6, 7, 8 in '042 do not expressly or
20 inherently disclose any weight in terms of kg and thus they cannot disclose any dose in terms of mg/kg/day. Similarly, examples 9-12 and the discussion in '042 at column 17, lines 38-47 describe dosages in terms of mg/day, but not in terms of mg/kg/day. Because the '042 patent does not expressly or inherently disclose any specific mg/kg/day dose, it cannot anticipate the dosages that the new
25 claims recite. *MEHL/Biophile, supra, Schering, supra*.

New claims 67-79 recite a treatment period of 3-15 consecutive days. The '042 patent does not disclose any specified time period for dosing and it thus cannot expressly or inherently anticipate any of new claims 67-79.

In view of the foregoing, Applicants respectfully request reconsideration
30 and withdrawal of the rejection.

Concluding remarks

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 501536.

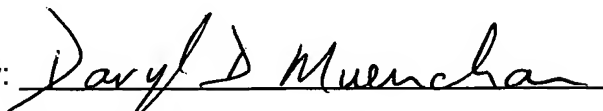
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Respectfully submitted,

Hollis-Eden Pharmaceuticals, Inc.

Date: September 21, 2005

By:



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Daryl D. Muenchau, Reg. No. 36,616
Hollis-Eden Pharmaceuticals, Inc.
4435 Eastgate Mall, Suite 400
San Diego, CA 92121
Phone: 858-320-2569
Fax: 858-558-6470

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